

1. Sanofi Defendants deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants admit that sanofi-aventis U.S. LLC labeled and distributed Taxotere®, a docetaxel product submitted under Section 505(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), as well as a docetaxel product submitted under Section 505(b) of the FDCA. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 1 directed to other parties, and therefore deny the same.

2. The allegations in Paragraph 2 do not contain a factual allegation directed toward Sanofi Defendants, and thus no response is required. To the extent a response is required, Sanofi Defendants deny that Plaintiffs are entitled to relief under the law of any jurisdiction under any choice of law analysis, including the laws of their home jurisdictions. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 and therefore deny the same.

3. The allegations in Paragraph 3 do not contain a factual allegation directed toward Sanofi Defendants, and thus no response is required. Sanofi Defendants also state that the allegations of Paragraph 3 are legal conclusions to which no response is required. To the extent a response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 and therefore deny the same.

INTRODUCTION

4. Sanofi Defendants admit that Taxotere® and/or docetaxel are prescription chemotherapy drugs indicated for treatment of certain cancers, including breast cancer. Sanofi Defendants deny the remaining allegations of Paragraph 4 and specifically deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient

to form a belief as to the truth of the allegations in Paragraph 4 directed to other parties, and therefore deny the same.

5. The allegations in Paragraph 5 do not contain a factual allegation directed toward Sanofi Defendants, and thus no response is required. To the extent a response is required, Sanofi Defendants deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 directed to other parties, and therefore deny the same.

6. Sanofi Defendants deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 6 and, therefore, deny the same.

7. Sanofi Defendants deny the allegations in Paragraph 7 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 7 directed to other parties and, therefore, deny the same.

THE PARTIES

A. Plaintiffs

8. Sanofi Defendants deny the allegations in Paragraph 8 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs or Plaintiffs' spouses, children, parents, decedents, wards and/or heirs, all represented by Plaintiffs' counsel whatsoever. Sanofi Defendants lack knowledge or information sufficient

to form a belief as to the truth of the allegations in Paragraph 8 directed to other parties, and therefore deny the same.

9. Sanofi Defendants deny the allegations in Paragraph 9 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 directed to other parties, and therefore deny the same.

10. The allegations of Paragraph 10 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants deny the allegations in Paragraph 10 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10, and therefore deny the same.

11. Sanofi Defendants deny the allegations in Paragraph 11 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 directed to other parties, and therefore deny the same.

B. Sanofi-Related Entities

12. Sanofi Defendants state that the allegations set forth in Paragraph 12 of Plaintiffs' Amended Master Complaint are no longer relevant to this action.³ To the extent a response is required, the allegations are directed to an entity other than Sanofi Defendants and, therefore, no response is required from Sanofi Defendants.

13. Sanofi Defendants state that the allegations set forth in Paragraph 12 of Plaintiffs' Amended Master Complaint are no longer relevant to this action. To the extent a response is required, the allegations are directed to an entity other than Sanofi Defendants and, therefore, no response is required from Sanofi Defendants.

14. Sanofi Defendants deny the allegations set forth in Paragraph 14 of Plaintiffs' Amended Master Complaint.

15. Sanofi Defendants admit that Sanofi US Services Inc. is a Delaware corporation with its principal place of business at 55 Corporate Drive in Bridgewater, New Jersey 08807, and that it is an indirect wholly owned subsidiary of Sanofi S.A. Sanofi Defendants deny the remaining allegations set forth in Paragraph 15.

16. Sanofi Defendants admit that sanofi-aventis U.S. LLC is a Delaware limited liability company with its principal place of business at 55 Corporate Drive in Bridgewater, New Jersey 08807. Sanofi Defendants state that sanofi-aventis U.S. LLC is a single-member LLC and its sole member is Sanofi US Services Inc., who has its principal place of business in New Jersey and is incorporated in the State of Delaware. Sanofi Defendants admit that sanofi-aventis U.S.

³ On April 28, 2017, named Defendants Sanofi (incorrectly named as Sanofi S.A.) and Aventis Pharma S.A. (collectively, the "French Defendants") moved to dismiss all claims asserted against them in MDL 2740 for lack of personal jurisdiction. Subsequently, the parties reached a stipulation whereby claims against these entities will be dismissed without prejudice. The parties anticipate filing this stipulation with the Court in the near future.

LLC engages in the labeling, advertising, marketing, promotion, sale and distribution of Taxotere[®] and/or docetaxel, consistent with the applicable indications for use. Sanofi Defendants deny the remaining allegations set forth in Paragraph 16.

17. Sanofi Defendants admit that sanofi-aventis U.S. LLC promotes, markets, distributes, and sells generic docetaxel in the United States. Sanofi Defendants admit that Winthrop U.S. is an operating division of sanofi-aventis U.S. LLC. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 17.

18. Sanofi Defendants state that sanofi-aventis U.S. LLC and Sanofi US Services Inc. are indirect subsidiaries of Sanofi (incorrectly named as Sanofi S.A.). Sanofi Defendants deny the remaining allegations set forth in Paragraph 18.

19. Sanofi Defendants state that the allegations set forth in Paragraph 19 of Plaintiffs' Amended Master Complaint are no longer relevant to this action. To the extent the allegations are directed to entities other than Sanofi Defendants, no response is required from Sanofi Defendants. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 19.

20. The allegations set forth in Paragraph 20 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 20 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 20.

21. The allegations set forth in Paragraph 21 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is

required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 21 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 21.

22. Sanofi Defendants state that the allegations set forth in Paragraph 22 of Plaintiffs' Amended Master Complaint are no longer relevant to this action, and, therefore, no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 22 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 22.

23. The allegations set forth in Paragraph 23 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations in Paragraph 23 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 23.

24. The allegations set forth in Paragraph 24 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations in Paragraph 24 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 24.

25. Sanofi Defendants state that the allegations set forth in Paragraph 25 of Plaintiffs' Amended Master Complaint are no longer relevant to this action. To the extent a response is required, the allegations are directed to an entity other than Sanofi Defendants and, therefore, no response is required from Sanofi Defendants. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 24.

26. The allegations set forth in Paragraph 26 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 26.

27. The allegations set forth in Paragraph 27 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants otherwise deny the allegations set forth in Paragraph 27.

28. The allegations set forth in Paragraph 28 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants otherwise deny the allegations set forth in Paragraph 28.

29. The allegations set forth in Paragraph 29 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations in Paragraph 29 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 29.

30. To the extent the allegations set forth in Paragraph 30 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, no response is required. To the extent a further response is required, Sanofi Defendants state that, sanofi-aventis U.S. LLC marketed Taxotere® and/or docetaxel in the United States. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 30.

31. The allegations set forth in Paragraph 31 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that sanofi-aventis U.S. LLC distributed and sold Taxotere® and/or docetaxel in the United States. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 31.

C. Other Brand Name Drug Sponsors, Manufacturers, Labelers, and Distributors

32. The allegations set forth in Paragraph 32 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 32 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

33. The allegations in Paragraph 33 of Plaintiffs' Amended Master Complaint contain legal conclusions to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 33 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 33 are denied.

34. The allegations in Paragraph 34 of Plaintiffs' Amended Master Complaint contain legal conclusions to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 34 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 34 are denied.

35. The allegations in Paragraph 35 of Plaintiffs' Amended Master Complaint contain legal conclusions to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 35 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 35 are denied.

36. The allegations in Paragraph 36 of Plaintiffs' Amended Master Complaint contain legal conclusions to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 36 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 36 are denied.

1. Sandoz

37. The allegations set forth in Paragraph 37 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is

required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 37 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

38. The allegations set forth in Paragraph 38 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 38 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

39. The allegations set forth in Paragraph 39 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 39 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

40. The allegations set forth in Paragraph 40 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 40 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

41. The allegations set forth in Paragraph 41 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 41 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

42. The allegations set forth in Paragraph 42 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 42 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

43. The allegations set forth in Paragraph 43 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 43 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

44. The allegations set forth in Paragraph 44 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 44 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

45. The allegations set forth in Paragraph 45 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 45 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

46. The allegations set forth in Paragraph 46 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations in Paragraph 46 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

47. The allegations set forth in Paragraph 47 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

48. The allegations set forth in Paragraph 48 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 48 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

49. The allegations set forth in Paragraph 49 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations in Paragraph 49 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 49 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

50. The allegations set forth in Paragraph 50 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations in Paragraph 50 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

2. *Accord Healthcare & McKesson*

51. The allegations set forth in Paragraph 51 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 51 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

52. The allegations set forth in Paragraph 52 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 52 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

53. The allegations set forth in Paragraph 53 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 53 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

54. The allegations set forth in Paragraph 54 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 54 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

55. The allegations set forth in Paragraph 55 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 55 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

56. The allegations set forth in Paragraph 56 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 56 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

57. The allegations set forth in Paragraph 57 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 57 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

58. The allegations set forth in Paragraph 58 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 58 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

59. The allegations set forth in Paragraph 59 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations in Paragraph 59 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

60. The allegations set forth in Paragraph 60 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations in Paragraph 60 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 60 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

61. The allegations set forth in Paragraph 61 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 61 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

62. The allegations set forth in Paragraph 62 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 62 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

63. The allegations set forth in Paragraph 63 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations

in Paragraph 63 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

4. *Hospira Entities*

64. The allegations set forth in Paragraph 64 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 64 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

65. The allegations set forth in Paragraph 65 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 65 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

66. The allegations set forth in Paragraph 66 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 66 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

67. The allegations set forth in Paragraph 67 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations in Paragraph 67 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

68. The allegations set forth in Paragraph 68 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

69. The allegations set forth in Paragraph 69 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

70. The allegations set forth in Paragraph 70 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the one-vial formulation of Taxotere[®] was approved by FDA in 2011, and that all one-vial Taxotere[®] labels state that they are for single use. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

71. The allegations set forth in Paragraph 71 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations in Paragraph 71 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

72. The allegations set forth in Paragraph 72 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations in Paragraph 72 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 72 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

73. The allegations set forth in Paragraph 73 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 73 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

74. The allegations set forth in Paragraph 74 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations in Paragraph 74 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 74 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

5. *Sun Pharma Entities*

75. The allegations set forth in Paragraph 75 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 32 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

76. The allegations set forth in Paragraph 76 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 76 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

77. The allegations set forth in Paragraph 77 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 77 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

78. The allegations set forth in Paragraph 78 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 78 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

79. The allegations set forth in Paragraph 79 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations in Paragraph 79 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

80. The allegations set forth in Paragraph 80 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 80 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

81. The allegations set forth in Paragraph 81 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the active ingredient solution for Taxotere[®] is viscous, and that the diluent contains 13 percent ethanol. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 81 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

82. The allegations set forth in Paragraph 82 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 82 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

83. The allegations set forth in Paragraph 83 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations in Paragraph 83 purport to quote, reference, interpret and/or paraphrase a document, and that the

complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 83 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

84. The allegations set forth in Paragraph 84 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 84 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

85. The allegations set forth in Paragraph 85 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 85 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

6. Pfizer

86. The allegations set forth in Paragraph 86 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 86 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

87. The allegations set forth in Paragraph 87 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations in Paragraph 87 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

88. The allegations set forth in Paragraph 88 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 88 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

89. The allegations set forth in Paragraph 89 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 89 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

90. The allegations set forth in Paragraph 90 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 90 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

91. The allegations set forth in Paragraph 91 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 91 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

92. The allegations set forth in Paragraph 92 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 92 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

93. The allegations set forth in Paragraph 93 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations in Paragraph 93 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 93 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

94. The allegations set forth in Paragraph 94 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 94 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

95. The allegations set forth in Paragraph 95 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 95 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

96. The allegations set forth in Paragraph 96 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 96 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

7. *Actavis Entities*

97. The allegations set forth in Paragraph 97 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 97 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

98. The allegations set forth in Paragraph 98 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 98 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

99. The allegations set forth in Paragraph 99 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 99 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

100. The allegations set forth in Paragraph 100 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations in Paragraph 100 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

101. The allegations set forth in Paragraph 101 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 101 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

102. The allegations set forth in Paragraph 102 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 102 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

103. The allegations set forth in Paragraph 103 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 103 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

104. The allegations set forth in Paragraph 104 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 104 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

105. The allegations set forth in Paragraph 105 of Plaintiffs' Amended Master Complaint are directed to an entity other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants state that the allegations in Paragraph 105 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 105 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

106. The allegations set forth in Paragraph 106 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 106 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

107. The allegations set forth in Paragraph 107 of Plaintiffs' Amended Master Complaint are directed to entities other than Sanofi Defendants, and, therefore, no response is required. To the extent further response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 107 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

JURISDICTION AND VENUE

108. The allegations of Paragraph 108 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants admit that federal subject matter jurisdiction is proper as to certain Plaintiffs and that Plaintiffs seek damages in excess of \$75,000, but deny that Plaintiffs are entitled to any relief whatsoever. Sanofi Defendants lack

knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 108 and, therefore, deny the same.

109. The allegations of Paragraph 109 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 109 and, therefore, deny the same.

110. The allegations of Paragraph 110 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants admit that venue of all actions pending in MDL 2740 is proper in the United States District Court for the Eastern District of Louisiana, pursuant to 28 U.S.C. § 1407.

111. The allegations of Paragraph 111 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants deny the allegations in Paragraph 11 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 111 directed to other parties and, therefore, deny the same.

FACTUAL ALLEGATIONS

A. Development, Approval, and Labeling Changes for Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez

112. Sanofi Defendants admit the allegations set forth in Paragraph 112 of Plaintiffs' Amended Master Complaint.

113. Sanofi Defendants generally admit that taxanes were originally derived from the Yew tree, inhibit the reproduction of cancer cells, and are widely used chemotherapy agents. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 113 and, therefore, deny the same.

114. Sanofi Defendants generally admit that the development of taxanes began approximately in the 1960s and that Bristol-Myers Squibb sold or distributed a taxane product known as Taxol or paclitaxel. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 114 and, therefore, deny the same.

115. Sanofi Defendants generally admit that Taxol was first approved for use in the United States on December 29, 1992. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 115 and, therefore, deny the same.

116. Sanofi Defendants generally admit generally that taxanes, including docetaxel, interfere with microtubule functioning that facilitates cancer cell reproduction. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 116 and, therefore, deny the same.

117. Sanofi Defendants admit that as first approved, Taxotere[®] for Injection Concentrate required dilution prior to use, and a sterile, non-pyrogenic, single-dose diluent was supplied for that purpose. Sanofi Defendants deny the remaining allegations set forth in Paragraph 117.

118. Sanofi Defendants admit that as first approved, Taxotere[®] for Injection Concentrate required dilution prior to use, and a sterile, non-pyrogenic, single-dose diluent was supplied for that purpose. Sanofi Defendants deny the remaining allegations set forth in Paragraph 118.

119. Sanofi Defendants deny the characterization in Paragraph 119 of the use and administration of their docetaxel products and state that the applicable product labeling speaks

for itself. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 119 directed to other named defendants, and therefore deny the same.

120. Sanofi Defendants deny that the entities listed in Paragraph 120 are a single entity or operate “collectively”. Sanofi Defendants further deny the allegations of Paragraph 120, as stated, related to the Taxotere patent. Sanofi Defendants deny the remaining allegations set forth in Paragraph 120.

121. Sanofi Defendants admit that a Phase I clinical study of docetaxel known as TAX 001 began in 1990 and was completed in 1992, and that a final report on that study was issued in May 1994. Sanofi Defendants otherwise deny the remaining allegations set forth in Paragraph 121.

122. Sanofi Defendants admit that a new drug application (“NDA”) for Taxotere[®] was submitted to the FDA in July 1994. Sanofi Defendants state that the allegations in Paragraph 122 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 122 are denied.

123. Sanofi Defendants admit that on May 14, 1996, the FDA approved Taxotere[®] (docetaxel) for the treatment of patients with locally advanced or metastatic breast cancer who have progressed during anthracycline-based therapy or have relapsed during anthracycline-based adjuvant therapy. Sanofi Defendants state that the allegations in Paragraph 123 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of

such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 123 are denied.

124. Sanofi Defendants admit that after initial FDA approval, Taxotere[®] received FDA approval for additional indications. Sanofi Defendants state that the remaining allegations in Paragraph 124 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 124 are denied.

125. Sanofi Defendants admit that on June 22, 1998, the FDA approved Taxotere[®] (docetaxel) for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy. Sanofi Defendants state that the allegations in Paragraph 125 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 125 are denied.

126. Sanofi Defendants admit that on December 23, 1999, the FDA approved Taxotere[®] (docetaxel) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy. Sanofi Defendants state that the allegations in Paragraph 126 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 126 are denied.

127. Sanofi Defendants admit that in November 2002, FDA approved the indication for Taxotere[®] to include first-line treatment. Sanofi Defendants deny the remaining allegations set forth in Paragraph 127.

128. Sanofi Defendants state that the allegations in Paragraph 128 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 128 are denied.

129. Sanofi Defendants admit that in November 2002, FDA approved Taxotere[®] (docetaxel) in combination with cisplatin for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer who have not previously received chemotherapy treatment. Sanofi Defendants state that the allegations in Paragraph 129 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 129 are denied.

130. Sanofi Defendants admit that in May 2004, FDA approved Taxotere[®] (docetaxel) in combination with prednisone for the treatment of patients with androgen independent (hormone refractory) metastatic prostate cancer. Sanofi Defendants state that the allegations in Paragraph 130 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 130 are denied.

131. Sanofi Defendants admit that in August 2004, FDA approved Taxotere[®] (docetaxel) in combination with doxorubicin and cyclophosphamide for the adjuvant treatment

of patients with operable node-positive breast cancer. Sanofi Defendants state that the allegations in Paragraph 131 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 131 are denied.

132. Sanofi Defendants admit that in March 2006, FDA approved Taxotere[®] (docetaxel) in combination with cisplatin and fluorouracil for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease. Sanofi Defendants state that the allegations in Paragraph 132 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 132 are denied.

133. Sanofi Defendants admit that in October 2006, FDA approved Taxotere[®] (docetaxel) in combination with cisplatin and fluorouracil for the induction treatment of patients with inoperable locally advanced squamous cell carcinoma of the head and neck (SCCHN). Sanofi Defendants further admit that in September 2007, FDA approved Taxotere[®] (docetaxel) in combination with cisplatin and fluorouracil for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN). Sanofi Defendants state that the allegations in Paragraph 133 purport to quote, reference, interpret and/or paraphrase documents, and that the complete and precise content of such documents can be ascertained from the documents themselves. Any characterization of the documents is denied. The remaining allegations of Paragraph 133 are denied.

134. Sanofi Defendants state that the allegations in Paragraph 134 purport to quote, reference, interpret and/or paraphrase documents, and that the complete and precise content of such documents can be ascertained from the documents themselves. Any characterization of the documents is denied. The remaining allegations of Paragraph 134 are denied.

135. Sanofi Defendants admit that FDA approved changes to the Taxotere[®] (docetaxel) package insert in May 2010. Sanofi Defendants state that the allegations in Paragraph 135 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 135 are denied.

136. Sanofi Defendants admit that in November 2015, sanofi-aventis U.S. LLC submitted a Labeling Supplement—Changes Being Effected for Taxotere[®] (docetaxel). Sanofi Defendants state that the allegations in Paragraph 136 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 136 are denied.

137. Sanofi Defendants admit that FDA approved changes to the Taxotere[®] (docetaxel) label in December 2015. Sanofi Defendants state that the allegations in Paragraph 137 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 137 are denied.

B. Defendants' Duties Under the FDCA and State Law

138. The allegations of Paragraph 138 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in

Paragraph 138 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 138 are denied.

139. The allegations of Paragraph 139 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 139 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 139 are denied.

140. The allegations of Paragraph 140 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 140 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 140 are denied.

141. The allegations of Paragraph 141 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 141 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 141 are denied.

142. The allegations of Paragraph 142 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 142 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 142 are denied.

143. The allegations of Paragraph 143 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 143 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 143 are denied.

144. The allegations of Paragraph 144 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 144 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 144 are denied.

145. The allegations of Paragraph 145 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 145 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be

ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 145 are denied.

146. The allegations of Paragraph 146 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that the allegations in Paragraph 146 purport to quote, reference, interpret and/or paraphrase federal statutes and/or regulations, and that the complete and precise content of such statutes and/or regulations can be ascertained from the statutes and/or regulations themselves. Any characterization of the statutes and/or regulations is denied. The remaining allegations of Paragraph 146 are denied.

147. Sanofi Defendants deny the allegations set forth in Paragraph 147 of Plaintiffs' Amended Master Complaint.

C. Defendants Knew That Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate May Cause Permanent Alopecia.

148. Sanofi Defendants admit that a company-sponsored trial entitled GEICAM 9805 compared the effects of a regimen of fluorouracil, doxorubicin, and cyclophosphamide ("FAC") with a regimen of docetaxel, doxorubicin, and cyclophosphamide ("TAC"). Sanofi Defendants further state that the allegations in Paragraph 148 purport to quote, reference, interpret and/or paraphrase a clinical study, and that the complete and precise content of such clinical study can be ascertained from the clinical study itself. Any characterization of the clinical study is denied. The remaining allegations of Paragraph 148 are denied.

149. Sanofi Defendants generally admit that Dr. Scot Sedlacek presented a study entitled "Persistent significant alopecia (PSA) from adjuvant docetaxel after doxorubicin/cyclophosphamide (AC) chemotherapy in women with breast cancer" in December 2006. Sanofi Defendants state that Plaintiffs' interpretations of and conclusions drawn from the

studies referenced in Paragraph 149 are erroneous and/or taken out of context, and the same are therefore denied. The remaining allegations of Paragraph 149 are denied.

150. Sanofi Defendants admit that a letter regarding a patient's concern with permanent alopecia was sent in November 2008. Sanofi Defendants further state that the allegations in Paragraph 150 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 150 are denied.

151. Sanofi Defendants generally admit that in 2009, the British Journal of Dermatology published an article entitled "Irreversible and severe alopecia following docetaxel or paclitaxel cytotoxic therapy for breast cancer." Sanofi Defendants further state that the allegations in Paragraph 151 purport to quote, reference, interpret and/or paraphrase an article, and that the complete and precise content of such article can be ascertained from the article itself. Any characterization of the article is denied. The remaining allegations of Paragraph 151 are denied.

152. Sanofi Defendants generally admit that on March 4, 2010, The Globe and Mail published an article entitled "Women who took chemo drug say they weren't warned of permanent hair loss." Sanofi Defendants further state that the allegations in Paragraph 152 purport to quote, reference, interpret and/or paraphrase an article, and that the complete and precise content of such article can be ascertained from the article itself. Any characterization of the article is denied. The remaining allegations of Paragraph 152 are denied.

153. Sanofi Defendants state that the allegations in Paragraph 153 purport to quote, reference, interpret and/or paraphrase an article, and that the complete and precise content of

such article can be ascertained from the article itself. Any characterization of the article is denied. The remaining allegations of Paragraph 153 are denied.

154. Sanofi Defendants generally admit that on March 6, 2010, CBS News published an article entitled “Sanofi’s Latest Challenge: Women Who Say Its Chemotherapy Left Them Permanently Bald.” Sanofi Defendants further state that the allegations in Paragraph 154 purport to quote, reference, interpret and/or paraphrase an article, and that the complete and precise content of such article can be ascertained from the article itself. Any characterization of the article is denied. The remaining allegations of Paragraph 154 are denied.

155. Sanofi Defendants state that the allegations in Paragraph 155 purport to quote, reference, interpret and/or paraphrase an article, and that the complete and precise content of such article can be ascertained from the article itself. Any characterization of the article is denied. The remaining allegations of Paragraph 155 are denied.

156. Sanofi Defendants generally admit that in May 2010, an article by Ben Tallon, MBChB, and others entitled “Permanent chemotherapy-induced alopecia: Case report and review of the literature” was published online. Sanofi Defendants further state that the allegations in Paragraph 156 purport to quote, reference, interpret and/or paraphrase an article, and that the complete and precise content of such article can be ascertained from the article itself. Any characterization of the article is denied. The remaining allegations of Paragraph 156 are denied.

157. Sanofi Defendants generally admit that In 2011, the American Journal of Dermatopathology published a study entitled “Permanent Alopecia After Systemic Chemotherapy: A Clinicopathological Study of 10 Cases,” by Mariya Miteva, MD and others. Sanofi Defendants further state that the allegations in Paragraph 157 purport to quote, reference,

interpret and/or paraphrase a study, and that the complete and precise content of such study can be ascertained from the study itself. Any characterization of the study is denied. The remaining allegations of Paragraph 157 are denied.

158. Sanofi Defendants generally admit that on May 9, 2012, the Annals of Oncology published an article entitled “Permanent scalp alopecia related to breast cancer chemotherapy by sequential fluorouracil/epirubicin/cyclophosphamide (FEC) and docetaxel: a prospective study of 20 patients.” Sanofi Defendants further state that the allegations in Paragraph 158 purport to quote, reference, interpret and/or paraphrase an article, and that the complete and precise content of such article can be ascertained from the article itself. Any characterization of the article is denied. The remaining allegations of Paragraph 158 are denied.

159. Sanofi Defendants generally admit that in October 2013, authors from the Clatterbridge Cancer Centre presented on “Long Term Hair Loss in Patients with Early Breast Cancer Receiving Docetaxel Chemotherapy.” Sanofi Defendants further state that the allegations in Paragraph 159 purport to quote, reference, interpret and/or paraphrase a study, and that the complete and precise content of such study can be ascertained from the study itself. Any characterization of the study is denied. The remaining allegations of Paragraph 159 are denied.

160. Sanofi Defendants generally admit that an abstract of the study referenced in Paragraph 113 was included in the San Antonio Breast Cancer Symposium in December 2014. Sanofi Defendants further state that the allegations in Paragraph 160 purport to quote, reference, interpret and/or paraphrase a study, and that the complete and precise content of such study can be ascertained from the study itself. Any characterization of the study is denied. The remaining allegations of Paragraph 160 are denied.

161. Sanofi Defendants generally admit that on November 10, 2015, the Journal of Clinical Oncology published an article entitled “Epirubicin Plus Cyclophosphamide Followed by Docetaxel Versus Epirubicin Plus Docetaxel Followed by Capecitabine As Adjuvant Therapy for Node-Positive Early Breast Cancer: Results From the GEICAM/2003-10 Study.” Sanofi Defendants state that the allegations in Paragraph 161 purport to quote, reference, interpret and/or paraphrase an article, and that the complete and precise content of such article can be ascertained from the article itself. Any characterization of the article is denied. The remaining allegations of Paragraph 161 are denied.

162. Sanofi Defendants generally admit that the Patient Information Leaflet in the Taxotere® label effective December 23, 1999 stated that hair generally grows back. Sanofi Defendants further state that the allegations in Paragraph 162 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 162 are denied.

163. Sanofi Defendants state that the allegations in Paragraph 163 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 163 are denied.

164. Sanofi Defendants generally admit that in the Highlights of Prescribing Information in the Taxotere® label effective September 28, 2007, alopecia is listed as a common adverse reaction. Sanofi Defendants further state that the allegations in Paragraph 164 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise

content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 164 are denied.

165. Sanofi Defendants generally admit that the Taxotere[®] label effective September 7, 2011 stated that side effects such as hair loss are associated with docetaxel administration, and that the most common side effects of Taxotere[®] include hair loss. Sanofi Defendants further state that the allegations in Paragraph 165 purport to quote, reference, interpret and/or paraphrase documents, and that the complete and precise content of such documents can be ascertained from the documents themselves. Any characterization of the documents is denied. The remaining allegations of Paragraph 165 are denied.

166. Sanofi Defendants state that the allegations in Paragraph 166 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 166 are denied.

167. Sanofi Defendants state that the allegations in Paragraph 167 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 167 are denied.

168. Sanofi Defendants state that the allegations in Paragraph 168 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 168 are denied.

169. Sanofi Defendants admit that in November 2015, sanofi-aventis U.S. LLC submitted a Labeling Supplement—Changes Being Effectuated for Taxotere[®] (docetaxel). Sanofi

Defendants state that the allegations in Paragraph 169 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 169 are denied.

170. Sanofi Defendants admit that the Taxotere[®] label effective December 11, 2015 states that cases of permanent hair loss have been reported, and that in some cases (frequency not known) permanent hair loss has been observed. Sanofi Defendants further state that the allegations in Paragraph 170 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 170 are denied.

171. Sanofi Defendants deny the allegations in Paragraph 171 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 171 directed to other parties, and therefore deny the same.

172. The allegations of Paragraph 172 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants deny the allegations contained in Paragraph 172 directed to them. Sanofi Defendants specifically deny that they or their product caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 172 directed at other parties, and on that basis deny the same.

173. Sanofi Defendants admit that chemotherapy can cause hair loss, which may be temporary. The remaining allegations of Paragraph 173 of Plaintiffs' Amended Master Complaint constitute medical conclusions to which no response is required. To the extent a response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 173 and therefore deny the same.

174. The allegations of Paragraph 174 of Plaintiffs' Amended Master Complaint constitute medical conclusions to which no response is required. To the extent a response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 174 and therefore deny the same.

175. The allegations of Paragraph 175 of Plaintiffs' Amended Master Complaint constitute medical conclusions to which no response is required. To the extent a response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 175 and therefore deny the same.

176. The allegations of Paragraph 176 of Plaintiffs' Amended Master Complaint constitute medical conclusions to which no response is required. To the extent a response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 176 and therefore deny the same.

177. The allegations of Paragraph 177 of Plaintiffs' Amended Master Complaint constitute medical conclusions to which no response is required. To the extent a response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 177 and therefore deny the same.

178. The allegations of Paragraph 178 of Plaintiffs' Amended Master Complaint constitute medical conclusions to which no response is required. To the extent a response is

required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 178 and therefore deny the same.

179. Sanofi Defendants state that the allegations in Paragraph 179 purport to quote, reference, interpret and/or paraphrase documents and/or articles, and that the complete and precise content of such documents and/or articles can be ascertained from the documents and/or articles themselves. Any characterization of the documents and/or articles is denied. The remaining allegations of Paragraph 179 constitute medical conclusions to which no response is required. To the extent a response is required, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 179 and therefore deny the same.

180. Sanofi Defendants state that Paragraph 180 attempts to characterize the side effects associated with docetaxel. Sanofi Defendants deny the characterization of the side effects of docetaxel in Paragraph 180, and states that the medical literature and applicable product labeling that contain information on the side effects of this drug speak for themselves. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 180 directed to other parties, and therefore denies the same. Sanofi Defendants deny the remaining allegations in Paragraph 180.

181. Sanofi Defendants state that the allegations in Paragraph 181 purport to quote, reference, interpret and/or paraphrase the experience of one unidentified oncologist, and that the complete and precise content of such experience can be ascertained from the unidentified oncologist himself. Any characterization of the unidentified oncologist's experience is denied. The remaining allegations of Paragraph 181 are denied.

182. Sanofi Defendants deny the allegations set forth in Paragraph 182. Sanofi Defendants further state that the allegations in Paragraph 182 purport to quote, reference, interpret and/or paraphrase a study, and that the complete and precise content of such study can be ascertained from the study itself. Any characterization of the study is denied.

183. Sanofi Defendants deny the allegations set forth in Paragraph 183. Sanofi Defendants further state that the allegations in Paragraph 183 purport to quote, reference, interpret and/or paraphrase a study, and that the complete and precise content of such study can be ascertained from the study itself. Any characterization of the study is denied.

184. Sanofi Defendants generally admit that an article by Ben Tallon and others entitled “Permanent chemotherapy-induced alopecia: Case report and review of the literature” exists. Sanofi Defendants state that the allegations in Paragraph 184 purport to quote, reference, interpret and/or paraphrase an article, and that the complete and precise content of such article can be ascertained from the article itself. Any characterization of the article is denied. The remaining allegations of Paragraph 184 are denied.

185. Sanofi Defendants generally admit that a study by Nicolas Kluger and others entitled “Permanent scalp alopecia related to breast cancer chemotherapy by sequential fluorouracil/epirubicin/cyclophosphamide (FEC) and docetaxel: a prospective study of 20 patients” exists. Sanofi Defendants state that the allegations in Paragraph 185 purport to quote, reference, interpret and/or paraphrase a study, and that the complete and precise content of such study can be ascertained from the study itself. Any characterization of the study is denied. The remaining allegations of Paragraph 185 are denied.

186. Sanofi Defendants generally admit that Drs. Thorp, Swift, Arundell, and Wong presented on “Long Term Hair Loss in Patients with Early Breast Cancer Receiving Docetaxel

Chemotherapy” in October 2013. Sanofi Defendants state that the allegations in Paragraph 186 purport to quote, reference, interpret and/or paraphrase a presentation, and that the complete and precise content of such presentation can be ascertained from the presentation itself. Any characterization of the presentation is denied. The remaining allegations of Paragraph 186 are denied.

187. Sanofi Defendants deny the allegations contained in Paragraph 187 directed to them. Sanofi Defendants specifically deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants further state that the allegations in Paragraph 187 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied.

188. Sanofi Defendants admit that the European Medicines Agency issued a report discussing Taxotere® on May 12, 2016. Sanofi Defendants further state that the allegations in Paragraph 188 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 188 are denied.

189. Sanofi Defendants deny the allegations contained in Paragraph 189 directed to them. Sanofi Defendants specifically deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 189 directed to other Defendants, and therefore deny the same.

D. Sanofi Marketed & Promoted Taxotere Despite Knowing It Caused Permanent Alopecia

190. Sanofi Defendants deny the allegations set forth in Paragraph 190 of Plaintiffs' Amended Master Complaint. Sanofi Defendants further state that the allegations in Paragraph 190 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied.

191. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 191 and, therefore, deny the same.

192. Sanofi Defendants admit that in 2000, Aventis Oncology launched an outreach program for breast cancer patients called "Connection Cards" to help women develop and maintain a network of resources and professional experts while undergoing breast cancer treatment. "Connections Cards" gift packages included various items, such as blank note cards and pre-paid domestic long distance calling cards. The remaining allegations of Paragraph 192 are denied.

193. Sanofi Defendants admit that in 2002, Sanofi Defendants produced some 60,000 "Connection Cards" gift packets, as well as transportation vouchers for taxi services and certificates for discounted medical wig purchases at wigs.com. The remaining allegations of Paragraph 193 are denied.

194. Sanofi Defendants admit that the "Connection Cards" gift package program successfully served the goal of helping women during cancer treatment and recovery, and that the program was repeated for multiple years. The remaining allegations of Paragraph 194 are denied.

195. Sanofi Defendants deny the allegations set forth in Paragraph 195 of Plaintiffs' Amended Master Complaint.

196. Sanofi Defendants deny the allegations set forth in Paragraph 196 of Plaintiffs' Amended Master Complaint.

197. Sanofi Defendants generally admit that the FDA sent a letter to Aventis Pharmaceuticals concerning promotional activities dated July 26, 2001. Sanofi Defendants further state that the allegations in Paragraph 197 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 197 are denied.

198. Sanofi Defendants generally admit that the FDA sent a letter to Aventis Pharmaceuticals concerning promotional activities dated July 26, 2001. Sanofi Defendants further state that the allegations in Paragraph 198 purport to quote, reference, interpret and/or paraphrase documents, and that the complete and precise content of such documents can be ascertained from the documents themselves. Any characterization of the documents is denied. The remaining allegations of Paragraph 198 are denied.

199. Sanofi Defendants generally admit that the FDA sent a letter to Aventis Pharmaceuticals concerning promotional activities dated July 26, 2001. Sanofi Defendants further state that the allegations in Paragraph 199 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 199 are denied.

200. Sanofi Defendants generally admit that the FDA sent a letter to Aventis Pharmaceuticals concerning promotional activities dated December 18, 2002. Sanofi Defendants further state that the allegations in Paragraph 200 purport to quote, reference, interpret and/or paraphrase documents, and that the complete and precise content of such documents can be ascertained from the documents themselves. Any characterization of the documents is denied. The remaining allegations of Paragraph 200 are denied.

201. Sanofi Defendants generally admit that Aventis Pharmaceuticals responded to FDA's letter of December 18, 2002 in a letter dated December 30, 2002. Sanofi Defendants further state that the allegations in Paragraph 201 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 201 are denied.

202. Sanofi Defendants generally admit that the FDA sent a letter to Aventis Pharmaceuticals concerning promotional activities dated July 17, 2003. Sanofi Defendants further state that the allegations in Paragraph 202 purport to quote, reference, interpret and/or paraphrase documents, and that the complete and precise content of such documents can be ascertained from the documents themselves. Any characterization of the documents is denied. The remaining allegations of Paragraph 202 are denied.

203. Sanofi Defendants generally admit that the FDA sent a letter to Aventis Pharmaceuticals concerning promotional activities dated July 17, 2003. Sanofi Defendants further state that the allegations in Paragraph 203 purport to quote, reference, interpret and/or paraphrase documents, and that the complete and precise content of such documents can be

ascertained from the documents themselves. Any characterization of the documents is denied. The remaining allegations of Paragraph 203 are denied.

204. Sanofi Defendants generally admit that Aventis Pharmaceuticals sent a letter to FDA concerning promotional materials dated August 1, 2003. Sanofi Defendants further state that the allegations in Paragraph 204 purport to quote, reference, interpret and/or paraphrase documents, and that the complete and precise content of such documents can be ascertained from the documents themselves. Any characterization of the documents is denied. The remaining allegations of Paragraph 204 are denied.

205. Sanofi Defendants generally admit that the FDA sent a letter to Aventis Pharmaceuticals concerning promotional activities dated November 12, 2003. Sanofi Defendants further state that the allegations in Paragraph 205 purport to quote, reference, interpret and/or paraphrase documents, and that the complete and precise content of such documents can be ascertained from the documents themselves. Any characterization of the documents is denied. The remaining allegations of Paragraph 205 are denied.

206. Sanofi Defendants deny the allegations set forth in Paragraph 206 of Plaintiffs' Amended Master Complaint.

207. Sanofi Defendants deny the allegations set forth in Paragraph 207 of Plaintiffs' Amended Master Complaint.

208. Sanofi Defendants state that the allegations in Paragraph 208 purport to quote, reference, interpret and/or paraphrase a study, and that the complete and precise content of such study can be ascertained from the study itself. Any characterization of the study is denied. The remaining allegations of Paragraph 208 are denied.

209. Sanofi Defendants deny the allegations in Paragraph 209 to the extent directed to Sanofi Defendants.

210. Sanofi Defendants state that the allegations in Paragraph 210 purport to quote, reference, interpret and/or paraphrase separate studies, and that the complete and precise content of such studies can be ascertained from the studies themselves. Any characterization of the studies is denied. The remaining allegations of Paragraph 210 are denied.

211. Sanofi Defendants state that the allegations in Paragraph 211 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of such document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 211 are denied.

212. Sanofi Defendants state that the allegations in Paragraph 212 purport to quote, reference, interpret and/or paraphrase advertisements, and that the complete and precise content of such advertisements can be ascertained from the advertisements themselves. Sanofi Defendants admit that television advertisements featuring the statements “Cancer is tough...but so are you!” and “Get the facts...share the feelings...look to the future...Sanofi Aventis—because health matters and so do you” were written. Any characterization of the advertisements is denied. The remaining allegations of Paragraph 212 are denied.

213. Sanofi Defendants state that the allegations in Paragraph 213 purport to quote, reference, interpret and/or paraphrase a study, and that the complete and precise content of such study can be ascertained from the study itself. Any characterization of the study is denied. The remaining allegations of Paragraph 213 are denied.

214. The allegations set forth in Paragraph 214 of Plaintiffs’ Amended Master Complaint are not directed to Sanofi Defendants, and, therefore, no response is required. To the

extent a response is required, Sanofi Defendants state that the allegations in Paragraph 214 purport to quote, reference, interpret and/or paraphrase studies, and that the complete and precise content of such studies can be ascertained from the studies themselves. Any characterization of the studies is denied. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 214 and, therefore, deny the same.

215. Sanofi Defendants state that the allegations set forth in Paragraph 215 are not directed at Sanofi Defendants. As such, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 215 and, therefore, deny the same.

216. Sanofi Defendants state that the allegations set forth in Paragraph 216 are not directed at Sanofi Defendants. As such, Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 216 and, therefore, deny the same.

217. Sanofi Defendants state that the allegations set forth in Paragraph 215 are not directed at Sanofi Defendants. As such, Sanofi Defendants state that the allegations in Paragraph 217 purport to quote, reference, interpret and/or paraphrase a study, and that the complete and precise content of such study can be ascertained from the study itself. Any characterization of the study is denied. The remaining allegations of Paragraph 217 are denied.

218. Sanofi Defendants deny the allegations of Paragraph 218.

219. Sanofi Defendants deny the allegations of Paragraph 219. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever.

FIRST CLAIM FOR RELIEF

(Strict Products Liability – Failure to Warn – Against All Defendants)

220. Sanofi Defendants hereby incorporate by reference their responses to each and every preceding Paragraph of this Amended Master Complaint as if fully set forth herein. However, to the extent this Paragraph contains new allegations, Sanofi Defendants deny the same.

221. Sanofi Defendants state that sanofi-aventis U.S. LLC has promoted, marketed, sold or distributed Taxotere[®] and/or docetaxel in the United States. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 221 involving other entities or products and therefore deny the same. Sanofi Defendants otherwise deny the allegations set forth in Paragraph 221.

222. Sanofi Defendants deny the allegations in Paragraph 222 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 222 directed to other parties, and therefore deny the same.

223. Sanofi Defendants admit that Winthrop U.S. is an operating division of sanofi-aventis U.S. LLC. Sanofi Defendants state that Winthrop docetaxel labeling is derived from the Taxotere[®] labeling. Sanofi Defendants otherwise deny the allegations set forth in Paragraph 223.

224. Sanofi Defendants deny the allegations in Paragraph 224 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 224 directed to other parties, and therefore deny the same.

225. Sanofi Defendants deny the allegations in Paragraph 225 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 225 directed to other parties, and therefore deny the same.

226. Sanofi Defendants deny the allegations in Paragraph 226 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 226 directed to other parties, and therefore deny the same.

227. Sanofi Defendants deny the allegations in Paragraph 227 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 227 directed to other parties, and therefore deny the same.

228. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 228 and, therefore, deny the same.

229. Sanofi Defendants deny the allegations in Paragraph 229 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 229 directed to other parties, and therefore deny the same.

230. Sanofi Defendants deny the allegations in Paragraph 230 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a

belief as to the truth of the allegations in Paragraph 230 directed to other parties, and therefore deny the same.

SECOND CLAIM FOR RELIEF

(Strict Products Liability for Misrepresentation – Against All Defendants)

Sanofi Defendants state that the Court dismissed Count 2 of Plaintiffs' First Amended Master Complaint in Pretrial Order No. 61, dated September 27, 2017, and therefore no answer is required. To the extent an answer is required, Sanofi Defendants deny the allegations contained in Paragraphs 231 – 238 of Plaintiffs' Amended Master Complaint.

THIRD CLAIM FOR RELIEF

(Negligence – Against All Defendants)

239. Sanofi Defendants hereby incorporate by reference their responses to each and every preceding Paragraph of this Amended Master Complaint as if fully set forth herein. However, to the extent this Paragraph contains new allegations, Sanofi Defendants deny the same.

240. The allegations of Paragraph 240 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that they complied with applicable legal duties, laws and regulatory obligations with respect to their docetaxel products.

241. Sanofi Defendants deny the allegations in Paragraph 241 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 241 directed to other parties, and therefore deny the same.

242. Sanofi Defendants deny the allegations in Paragraph 242, including all subparts therein, to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations in Paragraph 242 directed to other parties, and therefore deny the same.

243. Sanofi Defendants deny the allegations in Paragraph 243 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 243 directed to other parties, and therefore deny the same.

244. Sanofi Defendants deny the allegations in Paragraph 244 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 244 directed to other parties, and therefore deny the same.

245. Sanofi Defendants deny the allegations in Paragraph 245 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 245 directed to other parties, and therefore deny the same.

246. Sanofi Defendants deny the allegations in Paragraph 246 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 246 directed to other parties, and therefore deny the same.

FOURTH CLAIM FOR RELIEF

(Negligent Misrepresentation – Against All Defendants)

247. Sanofi Defendants hereby incorporate by reference their responses to each and every preceding Paragraph of this Amended Master Complaint as if fully set forth herein.

However, to the extent this Paragraph contains new allegations, Sanofi Defendants deny the same.

248. The allegations of Paragraph 248 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants state that they complied with applicable legal duties, laws and regulatory obligations with respect to their docetaxel products.

249. Sanofi Defendants deny the allegations in Paragraph 249 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 249 directed to other parties, and therefore deny the same.

250. Sanofi Defendants deny the allegations in Paragraph 250 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 250 directed to other parties, and therefore deny the same.

251. Sanofi Defendants deny the allegations in Paragraph 251 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 251 directed to other parties, and therefore deny the same.

252. Sanofi Defendants deny the allegations in Paragraph 252 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 252 directed to other parties, and therefore deny the same.

253. Sanofi Defendants deny the allegations in Paragraph 253 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief

as to the truth of the allegations in Paragraph 253 directed to other parties, and therefore deny the same.

254. Sanofi Defendants deny the allegations in Paragraph 254 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 254 directed to other parties, and therefore deny the same.

255. Sanofi Defendants deny the allegations in Paragraph 255 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 255 directed to other parties, and therefore deny the same.

256. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 256 of Plaintiffs' Amended Master Complaint and, therefore, deny the same.

257. Sanofi Defendants deny the allegations in Paragraph 257 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 257 directed to other parties, and therefore deny the same.

FIFTH CLAIM FOR RELIEF

(Fraudulent Misrepresentation – Against All Defendants)

258. Sanofi Defendants hereby incorporate by reference their responses to each and every preceding Paragraph of this Amended Master Complaint as if fully set forth herein.

However, to the extent this Paragraph contains new allegations, Sanofi Defendants deny the same.

259. Sanofi Defendants admit that sanofi-aventis U.S. LLC sold its docetaxel products to healthcare providers, which were accompanied by FDA-Approved labeling containing risks and benefits of the medication. Sanofi Defendants deny the remaining allegations contained in Paragraph 259.

260. Sanofi Defendants deny the allegations in Paragraph 260 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 260 directed to other parties, and therefore deny the same.

261. Sanofi Defendants deny the allegations in Paragraph 261 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 261 directed to other parties, and therefore deny the same.

262. Sanofi Defendants deny the allegations in Paragraph 262, including all subparts, to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 262 directed to other parties, and therefore deny the same.

263. Sanofi Defendants deny the allegations in Paragraph 263 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 263 directed to other parties, and therefore deny the same.

264. Sanofi Defendants deny the allegations in Paragraph 264 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 264 directed to other parties, and therefore deny the same.

265. Sanofi Defendants deny the allegations in Paragraph 265 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 265 directed to other parties, and therefore deny the same.

SIXTH CLAIM FOR RELIEF

(Fraudulent Concealment – Against All Defendants)

266. Sanofi Defendants hereby incorporate by reference their responses to each and every preceding Paragraph of this Amended Master Complaint as if fully set forth herein. However, to the extent this Paragraph contains new allegations, Sanofi Defendants deny the same.

267. Sanofi Defendants deny the allegations in Paragraph 267 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 267 directed to other parties, and therefore deny the same.

268. Sanofi Defendants deny the allegations in Paragraph 268 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 268 directed to other parties, and therefore deny the same.

269. Sanofi Defendants deny the allegations in Paragraph 269, including all subparts, to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 269 directed to other parties, and therefore deny the same.

270. Sanofi Defendants deny the allegations in Paragraph 270 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 270 directed to other parties, and therefore deny the same.

271. Sanofi Defendants deny the allegations in Paragraph 271 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 271 directed to other parties, and therefore deny the same.

272. Sanofi Defendants deny the allegations in Paragraph 272 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 272 directed to other parties, and therefore deny the same.

273. Sanofi Defendants deny the allegations in Paragraph 273 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 273 directed to other parties, and therefore deny the same.

274. Sanofi Defendants deny the allegations in Paragraph 274 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief

as to the truth of the allegations in Paragraph 274 directed to other parties, and therefore deny the same.

275. Sanofi Defendants deny the allegations in Paragraph 275 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 275 directed to other parties, and therefore deny the same.

SEVENTH CLAIM FOR RELIEF

(Fraud and Deceit – Against All Defendants)

276. Sanofi Defendants hereby incorporate by reference their responses to each and every preceding Paragraph of this Amended Master Complaint as if fully set forth herein. However, to the extent this Paragraph contains new allegations, Sanofi Defendants deny the same.

277. Sanofi Defendants deny the allegations in Paragraph 2 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 277 directed to other parties, and therefore deny the same.

278. Sanofi Defendants deny the allegations in Paragraph 278 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 278 directed to other parties, and therefore deny the same.

279. Sanofi Defendants deny the allegations in Paragraph 279 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief

as to the truth of the allegations in Paragraph 279 directed to other parties, and therefore deny the same.

280. Sanofi Defendants deny the allegations in Paragraph 280 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 280 directed to other parties, and therefore deny the same.

281. The allegations of Paragraph 281 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants deny the allegations in Paragraph 281 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 281 directed to other parties, and therefore deny the same.

282. The allegations of Paragraph 282 call for a legal conclusion to which no response is required. To the extent a response is required, Sanofi Defendants deny the allegations in Paragraph 282 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 282 directed to other parties, and therefore deny the same.

283. Sanofi Defendants deny the allegations in Paragraph 283 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 283 directed to other parties, and therefore deny the same.

284. Sanofi Defendants deny the allegations in Paragraph 284 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief

as to the truth of the allegations in Paragraph 284 directed to other parties, and therefore deny the same.

285. Sanofi Defendants deny the allegations in Paragraph 285 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 285 directed to other parties, and therefore deny the same.

286. Sanofi Defendants deny the allegations in Paragraph 286 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 286 directed to other parties, and therefore deny the same.

287. Sanofi Defendants deny the allegations in Paragraph 287 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 287 directed to other parties, and therefore deny the same.

288. Sanofi Defendants deny the allegations in Paragraph 288 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 288 directed to other parties, and therefore deny the same.

289. Sanofi Defendants deny the allegations in Paragraph 289 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 289 directed to other parties, and therefore deny the same.

290. Sanofi Defendants deny the allegations in Paragraph 290 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 290 directed to other parties, and therefore deny the same.

291. Sanofi Defendants deny the allegations in Paragraph 291 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 291 directed to other parties, and therefore deny the same.

292. Sanofi Defendants deny the allegations in Paragraph 292 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 292 directed to other parties, and therefore deny the same.

293. Sanofi Defendants deny the allegations in Paragraph 293 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 293 directed to other parties, and therefore deny the same.

294. Sanofi Defendants deny the allegations in Paragraph 294 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 294 directed to other parties, and therefore deny the same.

295. Sanofi Defendants deny the allegations in Paragraph 295 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief

as to the truth of the allegations in Paragraph 295 directed to other parties, and therefore deny the same.

296. Sanofi Defendants deny the allegations in Paragraph 296 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 296 directed to other parties, and therefore deny the same.

297. Sanofi Defendants deny the allegations in Paragraph 297 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 297 directed to other parties, and therefore deny the same.

298. Sanofi Defendants deny the allegations in Paragraph 298 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 298 directed to other parties, and therefore deny the same.

299. Sanofi Defendants deny the allegations in Paragraph 299 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 299 directed to other parties, and therefore deny the same.

300. Sanofi Defendants deny the allegations in Paragraph 300 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 300 directed to other parties, and therefore deny the same.

301. Sanofi Defendants deny the allegations in Paragraph 301 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 301 directed to other parties, and therefore deny the same.

302. Sanofi Defendants deny the allegations in Paragraph 302 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 302 directed to other parties, and therefore deny the same.

303. Sanofi Defendants deny the allegations in Paragraph 303 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 303 directed to other parties, and therefore deny the same.

304. Sanofi Defendants deny the allegations in Paragraph 304 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 304 directed to other parties, and therefore deny the same.

305. Sanofi Defendants deny the allegations in Paragraph 305 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 305 directed to other parties, and therefore deny the same.

306. Sanofi Defendants deny the allegations in Paragraph 306 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief

as to the truth of the allegations in Paragraph 306 directed to other parties, and therefore deny the same.

307. Sanofi Defendants deny the allegations in Paragraph 307 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 307 directed to other parties, and therefore deny the same.

308. Sanofi Defendants deny the allegations in Paragraph 308 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 308 directed to other parties, and therefore deny the same.

309. Sanofi Defendants deny the allegations in Paragraph 309 to the extent directed to Sanofi Defendants. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 309 directed to other parties, and therefore deny the same.

310. Sanofi Defendants deny the allegations in Paragraph 310 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 310 directed to other parties, and therefore deny the same.

EIGHTH CLAIM FOR RELIEF

(Breach of Express Warranty – Against Sanofi-Related Entities Only)

Sanofi Defendants state that the Court dismissed Count 8 of Plaintiffs' First Amended Master Complaint in Pretrial Order No. 61, dated September 27, 2017, and therefore no answer

is required. To the extent an answer is required, Sanofi Defendants deny the allegations contained in Paragraphs 311 – 318 of Plaintiffs' Plaintiffs' First Amended Master Complaint.

PRAYER FOR RELIEF

319. Sanofi Defendants deny the allegations in Paragraph 319 to the extent directed to Sanofi Defendants. Sanofi Defendants specifically deny that they or their docetaxel products caused Plaintiffs' alleged injuries and damages, and deny any wrongdoing or liability to Plaintiffs whatsoever. Sanofi Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 319 directed to other parties, and therefore deny the same.

JURY DEMAND

320. Sanofi Defendants request a trial by jury on all issues so triable, and reserve the right to seek to have a trial before twelve jurors.

AFFIRMATIVE DEFENSES

Having answered the allegations of Plaintiffs' Amended Master Complaint, and having denied any liability whatsoever, Sanofi Defendants further deny any allegations that have not been expressly admitted and assert the following affirmative defenses in response to the averments in Plaintiffs' Amended Master Complaint:

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Amended Master Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred for lack of personal jurisdiction and lack of subject matter jurisdiction.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs' Amended Master Complaint fails to state a claim upon which relief can be granted due to lack of adequate product identification.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' Amended Master Complaint must be dismissed because Plaintiffs provided insufficient process and/or insufficient service of process.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims have been improperly joined under the applicable rules of civil procedure and the applicable state and/or federal laws. The improper joinder of Plaintiffs'

causes of action violates the procedural and substantive due process rights of Sanofi Defendants under the Constitutions of the United States and the applicable states.

SEVENTH AFFIRMATIVE DEFENSE

Venue may be improper in any individual case in which the Plaintiff does not reside in the forum or cannot otherwise establish an independent basis for venue in that forum and any such Plaintiff's case should be dismissed on that basis. Plaintiffs' cases may be subject to dismissal or transfer under the doctrine of forum non conveniens.

EIGHTH AFFIRMATIVE DEFENSE

Sanofi Defendants assert any and all defenses available under Rule 12 of the Federal Rules of Civil Procedure.

NINTH AFFIRMATIVE DEFENSE

Sanofi Defendants assert any and all defenses available under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

TENTH AFFIRMATIVE DEFENSE

Sanofi Defendants assert any and all defenses available under the statutes and rules of each and every state and the United States as to any claim sounding in fraud.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are subsumed and/or barred, in whole or in part, by the product liability acts and statutes enacted in each state whose law is deemed to apply in this case. Alternatively, Plaintiffs cannot prevail on their claims under the product liability acts and statutes enacted in each state whose law is deemed to apply in this case, to the extent they failed to comply with the statutory prerequisites to such claim before they filed suit. Sanofi Defendants assert all available

defenses under the product liability acts and statutes of any state whose law is deemed to apply in this case.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs are barred from recovering against Sanofi Defendants because Plaintiffs' claims are expressly or impliedly preempted in accordance with the supremacy clause of the United States Constitution, by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and because of the pervasive federal regulation of prescription medications. Taxotere[®] and/or docetaxel has been approved for marketing in the United States by FDA and has been tested, manufactured and labeled in accordance with all applicable FDA standards and requirements. Further, there is no private cause of action provided for by the Food, Drug, and Cosmetic Act, and accordingly, Plaintiffs' claims are preempted. Plaintiffs' claims are additionally and specifically barred, in whole or in part, under *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001) and its progeny, and by the deference the common law gives in discretionary actions by the FDA under the Food, Drug, and Cosmetic Act. In the event that Plaintiffs' claims are not barred, Sanofi Defendants are entitled to a presumption that Taxotere[®] and/or docetaxel is free from any defect of defective condition.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.

FOURTEENTH AFFIRMATIVE DEFENSE

If Plaintiffs sustained injuries or incurred damages as alleged, such injuries or damages resulted from pre-existing or unrelated medical, genetic, or environmental conditions, diseases or illnesses of the Plaintiffs.

FIFTEENTH AFFIRMATIVE DEFENSE

The injuries and/or damages allegedly sustained by Plaintiffs were caused or contributed to be caused by third parties for whom Sanofi Defendants are not responsible and whom Sanofi Defendants have no right to control.

SIXTEENTH AFFIRMATIVE DEFENSE

Pursuant to state and other applicable federal and local rules and case law, if Plaintiffs suffered or sustained the loss, damage, injury, harm, expense, diminution, or deprivation alleged, which Sanofi Defendants deny, the same was caused in whole or in part or was contributed to by the negligence of Plaintiffs.

SEVENTEENTH AFFIRMATIVE DEFENSE

If any loss, damage, injury, harm, expense, diminution, or deprivation alleged by Plaintiffs was caused by any product manufactured or distributed by Sanofi Defendants, which Sanofi Defendants deny, the same was attributable to Plaintiffs' understanding and acceptance of the risks inherent in the taking of pharmaceutical products such as Taxotere[®] and/or docetaxel, including but not limited to the following:

- (a) the risks in particular persons of adverse side effects or reactions from pharmaceutical products;
- (b) the risks in particular persons that the pharmaceutical product will not effectively treat the condition for which the product was prescribed;
- (c) the risks inherent in the use of the referenced medication;
- (d) the side effects and risks associated with the medication which are contained in Sanofi Defendants' FDA-approved package insert for Taxotere[®] and/or docetaxel; and

- (e) the risks and warnings given to Plaintiffs by their health care providers prior to initiation of the medication.

EIGHTEENTH AFFIRMATIVE DEFENSE

If any loss, damage, injury, harm, expense, diminution, or deprivation alleged by Plaintiffs was caused by any product manufactured or distributed by Sanofi Defendants, which Sanofi Defendants deny, the same was attributable to Plaintiffs' misuse of the product, including but not limited to the following:

- (a) failing to seek timely medical advice and care;
- (b) failing to inform treating physicians and health care providers as to the true and complete nature of Plaintiffs' conditions;
- (c) failing to follow medical advice and instruction;
- (d) failing to take other medications in the manner and dosage prescribed;
- (e) misuse or abuse of Taxotere[®] and/or docetaxel;
- (f) alteration or negative use of Taxotere[®] and/or docetaxel;
- (g) failing to follow the package insert and prescriber's information for Taxotere[®] and/or docetaxel; and
- (f) failing to otherwise properly care for and preserve Plaintiffs' physical health.

NINETEENTH AFFIRMATIVE DEFENSE

The alleged injuries and damages of which Plaintiffs complain were not caused by any docetaxel product manufactured, sold, or distributed by Sanofi Defendants or any actions of Sanofi Defendants of any kind, but were caused by some other product, process, occurrence,

event, service, and/or person over which Sanofi Defendants exercised no control or right of control.

TWENTIETH AFFIRMATIVE DEFENSE

Some or all of Plaintiffs' claims for damages have not accrued and are too speculative, uncertain, and contingent to be recoverable.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Sanofi Defendants are liable only for damages found by the trier of fact equal to their percentage of responsibility, if any. Pursuant to Louisiana Civil Code article 2323, and any similar provisions under any applicable state law deemed to apply to the individual Plaintiffs' claims, if a person suffers injury, death, or loss as the result partly of her own negligence and partly as a result of the fault of another person or persons, the amount of damages recoverable shall be reduced in proportion to the degree or percentage of negligence attributable to the person suffering the injury, death, or loss. Furthermore, liability for damages caused by two or more persons shall be a joint and divisible obligation. *See, e.g.*, La. C.C. art. 2324. Furthermore, Sanofi Defendants contend that they shall not be solely liable with any other person for damages attributable to the fault of such other person, including the person suffering injury, death, or loss, regardless of such other person's insolvency, ability to pay, degree of fault, immunity by statute, or otherwise. *See, e.g., id.*

TWENTY-SECOND AFFIRMATIVE DEFENSE

Any recovery by Plaintiffs for medical or healthcare expenses should be limited to the amount actually paid or incurred. *See, e.g.*, La. C.C. art. 2315 and other applicable state laws. Specifically, Plaintiffs are not entitled to an award of damages for medical bills for which an

obligation to pay never existed, nor are they entitled to an award of damages for future medical bills.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, reduced, and/or limited pursuant to applicable statutory and common laws regarding limitation of awards, caps on recovery, and setoffs. Further, Plaintiffs are not entitled to collect an award of punitive damages because such an award would violate the due process, equal protection, and excessive fines clauses of the Louisiana and United States Constitutions and any similar provisions under any other state's law deemed to apply to the individual Plaintiffs' claims.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Sanofi Defendants further assert that any finding against them may not be based solely on evidence of a bad result to Plaintiffs, and assert their right to instructions to the fact finder in this regard.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Sanofi Defendants expressly invoke the procedural provisions authorized by the Louisiana Code of Civil Procedure Chapter 5, and any similar provisions under any applicable state law deemed to apply to the individual Plaintiffs' claims.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims against Sanofi Defendants are barred as Plaintiffs' alleged injuries and/or damages, if any, were proximately caused by intervening and/or superseding events (including acts and/or omissions) attributable to persons, firms, or corporations other than Sanofi Defendants, and any action or omission on the part of Sanofi Defendants was not the proximate cause of the alleged injuries and/or damages.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Upon information and belief, there exists no proximate causation between any alleged act, omission, breach of duty, or breach of warranty (none being admitted) by Sanofi Defendants and Plaintiffs' alleged damages, injuries, and/or losses, and all of Plaintiffs' alleged damages, injuries, and/or losses, if any, were the result of conduct by persons other than Sanofi Defendants.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Upon information and belief, the injuries, damages and/or losses sustained by Plaintiffs, if any, were directly or proximately caused by and contributed to by Plaintiffs' own negligence and comparative fault, and therefore any recovery should be diminished, reduced, offset, or barred in accordance with the principles of comparative fault and/or contributory negligence.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries and/or damages, if any, were caused by an idiosyncratic reaction, without any negligence, failure, or fault on the part of Sanofi Defendants or any defect attributable to Taxotere[®] and/or docetaxel.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries and/or damages, if any, were caused, or contributed to, by Plaintiffs' express or implied assumption of all risks. Upon information and belief, Plaintiffs were fully aware of and informed of all material facts and the nature of the risks of Taxotere[®] and/or docetaxel, and Plaintiffs accepted and assumed all of those risks.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of informed consent. Plaintiffs were informed of the risks associated with treatment and willingly consented to

treatment despite those risks. Specifically, Plaintiffs gave informed consent to their prescribing physicians before their alleged use of Taxotere[®] and/or docetaxel.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Sanofi Defendants' acts were at all times done reasonably, in good faith and without malice, with respect to each and every purported cause of action in Plaintiffs' Amended Master Complaint.

THIRTY-THIRD AFFIRMATIVE DEFENSE

At all relevant times during which Taxotere[®] and/or docetaxel was manufactured and sold, it was reasonably safe and reasonably fit for its intended use, was not defectively designed or manufactured, was not unreasonably dangerous, and was accompanied by proper warnings, labeling, packaging, information, and instructions, all in conformity with generally recognized prevailing industry and FDA standards and the state of the art in existence at the time.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

The injuries allegedly resulting from Plaintiffs' use of the products at issue were not foreseeable to Sanofi Defendants given the state of scientific knowledge and the state of the art at the time of the alleged injuries. At all times relevant, the products at issue conformed to state of the art specifications and state of scientific knowledge for such products at the time, as well as all applicable statutes and regulations, including those of the FDA.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because the benefits of Taxotere[®] and/or docetaxel outweigh any risk involved in using the medication.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Liability may not be imposed as to a properly manufactured prescription drug distributed with information regarding the risks of which the manufacturer knew at the time of the manufacture, and liability may not be imposed for untold risks not known at the time of such design, manufacture, and sale of the subject prescription drug.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because Taxotere[®] and/or docetaxel, and its warnings and accompanying information, complied with federal, state and administrative regulations and applicable industry standards at the time of its manufacture.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' Amended Master Complaint fails to state a claim upon which relief can be granted because the methods, standards, and techniques utilized by Sanofi Defendants in manufacturing, distributing, marketing, or labeling Taxotere[®] and/or docetaxel and in issuing warnings and instructions with respect to its use, conformed with the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured and distributed.

THIRTY-NINTH AFFIRMATIVE DEFENSE

Taxotere[®] and/or docetaxel is a prescription medical product that is neither defective nor unreasonably dangerous because it is a product falling within the *comment j* and *comment k* exceptions to strict tort liability as defined by Restatement (Second) of Torts Section 402A.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries and/or damages were the result of an unavoidable accident.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims of product defect are or may be barred by the doctrine described in Section 4 of the Restatement (Third) of Torts: Products Liability, because Defendant and Taxotere[®] and/or docetaxel complied with applicable product safety statutes and administrative regulations. Taxotere[®] and/or docetaxel, an FDA-approved prescription drug, was prepared and labeled in accordance with applicable statutes and regulations.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs fail to state a claim upon which relief can be granted because manufacturers and distributors of prescription drugs such as Taxotere[®] and/or docetaxel have no legal duty to warn the patient, as opposed to the patient's physician, of risks inherent in the use of a prescription drug. Plaintiffs' claims are barred by virtue of the intervention of a learned intermediary or intermediaries to whom Defendant discharged its duties to warn. Upon information and belief, Plaintiffs were at all relevant times under the care and treatment of licensed physicians who prescribed the medication at issue. Plaintiffs readily admit that the drugs at issue are not purchased by patients at a pharmacy, but rather administered via injection and/or intravenously at a physician's office or medical treatment facility. If Plaintiffs were injured by the Sanofi Defendants' medication, which the Sanofi Defendants deny, Sanofi Defendants fully informed and disclosed to the physician(s) caring for Plaintiffs all relevant information necessary to warn Plaintiffs of any risks associated with using the product. The physicians caring for Plaintiffs had a duty to warn them of the risks associated with using the medication at issue. As such, Plaintiffs' claims are barred, in whole or in part, by the learned intermediary doctrine. Plaintiffs' claims are also barred by the Sophisticated User Doctrine or similar applicable laws.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claim for fraud must be dismissed due to Plaintiffs' failure to plead such cause of action with the particularity required by Fed. R. Civ. P. 9(b). Further, Plaintiffs' causes of action for fraudulent misrepresentation and concealment, negligent misrepresentation, and any additional allegations sounding in fraud in Plaintiffs' Amended Master Complaint are defective due to Plaintiffs' failure to plead such claims with the particularity required by Fed. R. Civ. P. 9(b).

FORTY-FOURTH AFFIRMATIVE DEFENSE

If any loss, damage, injury, harm, expense, diminution, or deprivation alleged by Plaintiffs were caused by any product manufactured or distributed by Sanofi Defendants, which Sanofi Defendants deny, the actions or omissions of other persons and the independent knowledge and awareness of such other persons of the risks inherent in the use of such products and other independent causes, such as idiosyncratic reactions, pre-existing or co-existing medical conditions, constitute intervening and/or superseding causes between Plaintiffs' alleged injuries and any alleged acts, conduct, or omissions of Sanofi Defendants.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Sanofi Defendants complied with all applicable statutes and with FDA requirements and regulations.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred because a reasonable purchaser and/or consumer would have been aware of the risks associated with Taxotere® and/or docetaxel.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Any dangers associated with the use of Taxotere[®] and/or docetaxel, if any, were open and obvious, and Plaintiffs are therefore barred from recovery.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries and/or damages, if caused by Taxotere[®] and/or docetaxel, which Sanofi Defendants deny, were caused by an inherent characteristic of Taxotere[®] and/or docetaxel which is a generic aspect of the medication that could not be eliminated without substantially compromising Taxotere[®] and/or docetaxel's usefulness or desirability and that is recognized by the ordinary person with the ordinary knowledge common to the community.

FORTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' product liability cause of action is barred because, at the time Taxotere[®] and/or docetaxel left Sanofi Defendants' control, a practical and technically feasible alternative design or formulation was not available that would have prevented Plaintiffs' alleged injuries and/or damages without substantially impairing the usefulness or intended purpose of Taxotere[®] and/or docetaxel.

FIFTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by Plaintiffs' failure to assert a safer alternative design for any of the products at issue.

FIFTY-FIRST AFFIRMATIVE DEFENSE

Based on the state of scientific, medical, and technological knowledge at the time Taxotere[®] and/or docetaxel was marketed, it was reasonably safe for normal and foreseeable use at all relevant times; any risk could not have been avoided through use of the highest standards

of scientific and technical knowledge available at the time, and the benefit provided to users could not have been achieved in another manner with less risk.

FIFTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because Taxotere[®] and/or docetaxel may have been substantially modified and/or altered.

FIFTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' breach of warranty claims are barred by a lack of privity between Plaintiffs and Sanofi Defendants.

FIFTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' breach of warranty claims are barred because Plaintiffs failed to provide Sanofi Defendants with reasonable, adequate, and/or timely notice of the alleged breach of any such purported warranties; Plaintiffs did not reasonably rely upon any alleged warranty; Plaintiffs failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty; and any such warranty was appropriately disclaimed, excluded or modified.

FIFTY-FIFTH AFFIRMATIVE DEFENSE

Sanofi Defendants had no actual or constructive notice of the alleged defects referred to in Plaintiffs' Amended Master Complaint.

FIFTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs did not rely on any alleged express or implied warranty or other act, representation, or omission by Sanofi Defendants.

FIFTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Sanofi Defendants made no false or misleading representations or omissions of any nature whatsoever to Plaintiffs.

FIFTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the commercial speech of Sanofi Defendants relating to Taxotere® and/or docetaxel is protected under the First Amendment of the United States Constitution and under the applicable state constitutions.

FIFTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the doctrine of immunity for prescription drugs, by the Commerce Clause, Article 1, Section 8 of the United States Constitution as an undue burden upon interstate commerce in that Plaintiffs have asserted claims for relief which, if granted, would constitute an impermissible burden on federal laws, regulations and policy relating to the development and marketing of prescription drugs in violation of the Supremacy Clause, Article VI, Clause 2 of the United States Constitution.

SIXTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by the doctrines of waiver, estoppel, and/or laches and/or statutory and regulatory compliance.

SIXTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the doctrines of release, accord, and satisfaction.

SIXTY-SECOND AFFIRMATIVE DEFENSE

Some or all of Plaintiffs' claims are barred by collateral estoppel and res judicata.

SIXTY-THIRD AFFIRMATIVE DEFENSE

Some or all of Plaintiffs' claims are barred by their failure to comply with conditions precedent to their right to recover.

SIXTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' negligence claims are barred, in whole or in part, because Sanofi Defendants did not owe or assume any duty to Plaintiffs, and Sanofi Defendants have no legal relationship, special relationship, and/or privity with Plaintiffs by which liability can be attributed to it.

SIXTY-FIFTH AFFIRMATIVE DEFENSE

To the extent any duty is found to exist, Sanofi Defendants deny that they breached any duty to Plaintiffs.

SIXTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' negligence claims are barred, in whole or in part, to the extent that Sanofi Defendants show that, at all times relevant to the claims in the Amended Master Complaint, they met or exceeded the requisite standard of care.

SIXTY-SEVENTH AFFIRMATIVE DEFENSE

While denying any alleged representations or misrepresentations as stated in Plaintiffs' Amended Master Complaint, Plaintiffs' claims are barred as a result of failure to plead with particularity Plaintiffs' and/or their treating and prescribing physicians' reliance on any such alleged representations.

SIXTY-EIGHTH AFFIRMATIVE DEFENSE

As to any claim alleging a violation of the consumer protection laws of any state whose law is deemed to apply in this case, Sanofi Defendants specifically plead all affirmative defenses available to Sanofi Defendants under the rules and statutes of any state whose law is deemed to

apply in this case, and under the common law of any state whose law is deemed to apply in this case.

SIXTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to satisfaction under the consumer protection laws of any state because Plaintiffs cannot satisfy the elements of these statutes and because Plaintiffs lack standing to assert claims under these statutes.

SEVENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the doctrines described in Section 6 of the Restatement (Third) of Torts: Products Liability. Reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with Taxotere[®] and/or docetaxel would have prescribed and did prescribe Taxotere[®] and/or docetaxel for classes of patients, including Plaintiffs. In addition, Sanofi Defendants provided prescribing physicians with reasonable instructions or warnings regarding foreseeable risks of harm.

SEVENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' damages are limited by their failure to reasonably mitigate damages.

SEVENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims for equitable relief are barred because equitable relief is not available under any of the alleged causes of action, and Plaintiffs' have an adequate remedy at law.

SEVENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to an award of attorneys' fees in the absence of a contract, statute, or law authorizing such fees.

SEVENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are subject to reduction for payments from collateral sources. Any recovery by Plaintiffs must be reduced or offset by amounts Plaintiffs have received or will receive from others for the same injuries claimed in this lawsuit.

SEVENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' damages are restricted by applicable limits on recovery for non-economic loss or injury.

SEVENTY-SIXTH AFFIRMATIVE DEFENSE

Sanofi Defendants specifically pleads all defenses available to it under the rules, statutes, and constitutional provisions of each any every state with respect to claims for punitive damages.

SEVENTY-SEVENTH AFFIRMATIVE DEFENSE

While Sanofi Defendants deny that they are liable for any punitive damages in this case, Sanofi Defendants further state that any award of punitive damages cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, an award of punitive damages; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Defendant; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiffs' burden

of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Sanofi Defendants' due process and equal protection rights guaranteed by the Fifth and the Fourteenth Amendments to the United States Constitution and would violate cognate provisions of state constitutions, and would be improper under applicable common law and public policies.

SEVENTY-EIGHTH AFFIRMATIVE DEFENSE

While Sanofi Defendants deny that they are liable for any punitive damages in this case, Sanofi Defendants state that Plaintiffs' claims for punitive damages cannot be sustained because an award of punitive damages, subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose and providing no protection against multiple awards for the same course of conduct, would violate Sanofi Defendants' due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would also violate Sanofi Defendants' right not to be subjected to an excessive award in violation of the Eighth Amendment to the United States Constitution and would violate cognate provisions of state constitutions.

SEVENTY-NINTH AFFIRMATIVE DEFENSE

While Sanofi Defendants deny that they are liable for any punitive damages in this case, Plaintiffs' claims for punitive damages cannot be sustained because any award of punitive damages, which are penal in nature, without according to Sanofi Defendants the same protections that are accorded to criminal defendants, including the protection against unreasonable searches and seizures, self-incrimination, double jeopardy, the right to confront

adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Sanofi Defendants' rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and cognate provisions of state constitutions.

EIGHTIETH AFFIRMATIVE DEFENSE

While Sanofi Defendants deny that they are liable for any punitive damages in this case, Plaintiffs' claims for punitive damages cannot be sustained because an award of punitive damages would violate Sanofi Defendants' rights guaranteed by the Due Process Clause of the Fourteenth Amendment to the United States Constitution and cognate provisions of state constitutions. The Due Process Clause requires that adversarial proceedings be fundamentally fair. It would violate fundamental fairness to permit Sanofi Defendants to be punished by way of an award of punitive damages in this action.

EIGHTY-FIRST AFFIRMATIVE DEFENSE

While Sanofi Defendants deny that they are liable for any punitive damages in this case, Plaintiffs' claims for punitive damages cannot be sustained because an award of punitive damages would violate Sanofi Defendants' rights guaranteed by the Due Process, Double Jeopardy, Excessive Fines, and Equal Protection Clauses of the Fifth, Eighth, and Fourteenth Amendments of the United States Constitution; the constitutions of the 50 states; and the law, statutes, rules, and policies of the United States and the several states under the circumstances of this case where: (1) punitive damages are imposed, and the amount of an award thereof is determined under impermissibly vague, imprecise, or inconsistent applicable state law; (2) punitive damages are imposed, and the amount of an award thereof is determined, without bifurcating the trial and trying all punitive damages issues only if and after the liability of Sanofi

Defendants were determined on the merits; (3) punitive damages are imposed, and the amount of an award thereof is determined, based on anything other than Sanofi Defendants' conduct in connection with the sale of the specific products alleged in this litigation; and/or (4) Sanofi Defendants are otherwise or in any way subjected to impermissible multiple punishment for the same alleged wrong.

EIGHTY-SECOND AFFIRMATIVE DEFENSE

While Sanofi Defendants deny that they are liable for any punitive damages in this case, Plaintiffs' claims for punitive damages cannot be sustained to the extent it seeks to punish Sanofi Defendants for the alleged conduct of non-parties and/or persons who are not before the Court, or for alleged harm to non-parties and/or persons who are not before the Court. Imposition of punitive damages under such circumstances would violate Sanofi Defendants' procedural and substantive due process rights and equal protection rights under the Fifth and Fourteenth Amendments to the United States Constitution and cognate provisions of state constitutions, and would be improper under the common law and public policies of the United States and the 50 states.

EIGHTY-THIRD AFFIRMATIVE DEFENSE

Sanofi Defendants specifically incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damages awards, including but not limited to, those standards of limitation which arose in *Smith v. Wade*, 461 U.S. 30 (1983); *Molzof v. United States*, 502 U.S. 301 (1992); *BMW of North America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris v. Williams*, 127 S. Ct. 1057 (2007).

EIGHTY-FOURTH AFFIRMATIVE DEFENSE

No act or omission of Sanofi Defendants was malicious, wanton, reckless, callous, grossly negligent, purposeful, or intentional, or due to oppression, fraud, an evil motive or a reckless or depraved indifference to the rights of others; therefore, any award of punitive damages is barred.

EIGHTY-FIFTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations made to FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

EIGHTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because FDA has exclusive or primary jurisdiction over the matters asserted in Plaintiffs' Amended Master Complaint.

EIGHTY-SEVENTH AFFIRMATIVE DEFENSE

The statutes upon which Plaintiffs base their Complaint are unconstitutionally vague and ambiguous on their face as applied to Sanofi Defendants. The statutes do not provide sufficient notice as to what constitutes a violation. Sanofi Defendants were justified in relying on a reasonable interpretation of the statutes. A finding of liability against Sanofi Defendants based upon the application of the facts at bar would violate Sanofi Defendants' rights under the Due Process Clause of the Fourteenth Amendment to the United States Constitution and cognate provisions of state constitutions.

EIGHTY-EIGHTH AFFIRMATIVE DEFENSE

While Sanofi Defendants deny that they are liable for any punitive damages in this case, Sanofi Defendants further state that the correct standard for submitting Plaintiffs' burden of

proof for punitive damages is “clear and convincing evidence.” Any lesser standard is in violation of the due process clause of the Fourteenth Amendment of the United States Constitution and cognate provisions of state constitutions.

EIGHTY-NINTH AFFIRMATIVE DEFENSE

While Sanofi Defendants deny that they are liable for any punitive damages in this case, the Sixth Amendment to the United States Constitution and cognate provisions of state constitutions prohibit any award of punitive damages unless there is a unanimous verdict.

NINETIETH AFFIRMATIVE DEFENSE

The injuries or damages sustained by Plaintiffs, if any, can be attributed to several causes, and accordingly, should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained.

NINETY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs’ causes of action are barred, in whole or in part, and the recoverable damages, if any, should be apportioned or diminished, because the fault, negligence and culpable conduct of parties or non-parties over whom Sanofi Defendants have no control and no responsibility caused or contributed to the injuries and damages allegedly sustained.

NINETY-SECOND AFFIRMATIVE DEFENSE

The United States District Court in which the action was originally filed or removed to, or in which Plaintiffs would have otherwise filed absent MDL Pretrial Order No. 4 (Rec. Doc. No. 122) is an improper and/or inconvenient venue.

NINETY-THIRD AFFIRMATIVE DEFENSE

Sanofi Defendants assert the provisions of all applicable statutory caps on damages of any sort under the laws of each and every state whose law is deemed to apply in this case.

NINETY-FOURTH AFFIRMATIVE DEFENSE

Sanofi Defendants are entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiffs with any other person or entity.

NINETY-FIFTH AFFIRMATIVE DEFENSE

Sanofi Defendants assert any and all defenses that might apply to this action by virtue of applicable state law.

NINETY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for relief are barred by the applicable state statutes of limitations and/or repose.

NINETY-SEVENTH AFFIRMATIVE DEFENSE

Sanofi Defendants hereby give notice that they intend to rely upon such other defenses as may become available or appear during the course of discovery proceedings in this case and hereby reserve the right to amend this Master Answer to assert such defenses. Additionally, Sanofi Defendants hereby give notice that they intend to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

WHEREFORE, Sanofi Defendants pray:

1. That Plaintiffs take nothing by reason of their Master Complaint;
2. That judgment enter in their favor and against Plaintiffs;
3. That this Court award Sanofi Defendants any such other further relief as this Court deems just and proper.

JURY DEMAND

Sanofi Defendants demand a trial by jury of all issues so triable, and reserve the right to seek to have a trial before twelve jurors.

Respectfully submitted,

/s/ Douglas J. Moore

Douglas J. Moore (Bar No. 27706)

IRWIN FRITCHIE URQUHART & MOORE LLC

400 Poydras Street, Suite 2700

New Orleans, LA 70130

Telephone: 504-310-2100

Facsimile: 504-310-2120

dmoore@irwinllc.com

Harley Ratliff

Adrienne L. Byard

SHOOK, HARDY & BACON L.L.P.

2555 Grand Boulevard

Kansas City, Missouri 64108

Telephone: 816-474-6550

Facsimile: 816-421-5547

hratliff@shb.com

Counsel for sanofi-aventis U.S. LLC

CERTIFICATE OF SERVICE

I hereby certify that on October 16, 2017, I electronically filed the foregoing with the Clerk of the Court using the ECF system which sent notification of such filing to all counsel of record.

/s/ Douglas J. Moore